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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/735,916

12/16/2003

Liliane Goetsch

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EXAMINER

HUYNH, PHUONG N

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/735,916		GOETSCH ET AL.	
	Examiner		Art Unit	
	Phuong Huynh		1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE One MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/16/03.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-54 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

- I. Claims 1-54 are pending.

Election/Restrictions

- II. Restriction to one of the following inventions is required under 35 U.S.C. 121 and 372:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1:

1. Claims 1-17, 22-30, and 43-54, drawn to an **isolated antibody**, or one of its functional fragments that binds human insulin-like growth factor T receptor and inhibits the natural attachment of its ligands IGF1 and /or IGF2 and/or capable of specific the tyrosine kinase activity of said receptor, a hybridoma producing said antibody, a process of producing said antibody, a composition comprising said antibody or functional fragments thereof and a pharmaceutically acceptable carrier, a method for the preparation of a medicament using said antibody and a kit comprising said antibody.
2. Claims 18-20, drawn to an isolated **nucleic acid** encoding an isolated antibody, or one of its functional fragments that binds human insulin-like growth factor T receptor and inhibits the natural attachment of its ligands IGF1 and /or IGF2 and/or capable of specific the tyrosine kinase activity of said receptor, vector comprising said nucleic acid, and host cell comprising said vector.
3. Claim 21, drawn to a **transgenic animal** comprising at least one cell transformed by a vector comprising isolated nucleic acid encoding an isolated antibody, or one of its functional fragments that binds human insulin-like growth factor T receptor and inhibits the natural attachment of its ligands IGF1 and /or IGF2 and/or capable of specific the tyrosine kinase activity of said receptor.
4. Claims 31-35, and 43-44, drawn to a **composition comprising an isolated antibody**, or one of its functional fragments **that binds human insulin-like growth factor T receptor** and inhibits the natural attachment of its ligands IGF1 and /or IGF2 and/or capable of

specific the tyrosine kinase activity of said receptor and a second compound that inhibits the attachment of the EGF to the human EGFR and/or capable of specifically inhibiting the tyrosine kinase activity of said EGFR, **and a second compound wherein the second compound is an anti-EGFR antibodies or functional fragment thereof.**

5. Claims 36-39, and 43-44, drawn to a **composition comprising an isolated antibody, or one of its functional fragments that binds human insulin-like growth factor T receptor** and inhibits the natural attachment of its ligands IGF1 and /or IGF2 and/or capable of specific the tyrosine kinase activity of said receptor and a second compound that inhibits the attachment of the EGF to the human EGFR and/or capable of specifically inhibiting the tyrosine kinase activity of said EGFR, **and a second compound wherein the second compound is a cytotoxic/cytostatic agent.**
6. Claims 36, 40, and 43-44, drawn to a **composition comprising an isolated antibody, or one of its functional fragments that binds human insulin-like growth factor T receptor** and inhibits the natural attachment of its ligands IGF1 and /or IGF2 and/or capable of specific the tyrosine kinase activity of said receptor and a second compound that inhibits the attachment of the EGF to the human EGFR and/or capable of specifically inhibiting the tyrosine kinase activity of said EGFR, **and a second compound wherein the second compound is an inhibitor of tyrosine kinase activity.**
7. Claims 41-44, drawn to a **composition comprising an isolated antibody, or one of its functional fragments that binds human insulin-like growth factor T receptor** and inhibits the natural attachment of its ligands IGF1 and /or IGF2 and/or capable of specific the tyrosine kinase activity of said receptor and a second compound that inhibits the attachment of the EGF to the human EGFR and/or capable of specifically inhibiting the tyrosine kinase activity of said EGFR, **and a second compound wherein the second compound is another antibody that directed against the extracellular domain of the HER2/neu receptor.**

Linking claim 30 will be examined along with Groups 4-7 if any one of said Groups is elected.

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Claim 30 link inventions 4, 5, 6 and 7. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim 30. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

III. The inventions listed as Groups 1-7 do not relate to a single general inventive concept under PCT Rule 13.1 because, under unity of invention practice as it applies to cases filed under 35 U.S.C. 371, unity of invention between different categories of inventions will only be found to exist if specific combinations of inventions are present. Those combinations include:

- A) A product and a special process of manufacture of said product.
- B) A product and a process of use of said product.
- C) A product, a special process of manufacture of said product and a process of use of said product.
- D) A process and an apparatus specially designed to carry out said process.
- E) A product, a special process of manufacture of said product, and an apparatus specially designed to carry out said process.

The allowed combinations do not include multiple products, multiple methods of using said products, and a method of making a product as claimed in the instant application, see MPEP § 1850).

IV. Accordingly, Groups 1-7 are not so linked as to form a single general inventive concept and restriction is proper.

V. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

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- VI. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

- VII. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The IFW official Fax number is (571) 273-8300.

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VIII. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phuong N. Huynh, Ph.D.

Patent Examiner

Technology Center 1600

October 28, 2005


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